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IN THE

# Supreme Court of the United States

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ANDRX PHARMACEUTICALS, INC.,
*Petitioner*,

v.

BIOVAIL CORPORATION,
*Respondent*.

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**On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit**

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## PETITION FOR WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

Petitioner, a manufacturer of generic drugs, entered into an interim settlement of a patent infringement action in which it agreed to maintain the status quo by not selling an allegedly infringing product during the pendency of patent infringement litigation. The stipulation embodying the interim settlement agreement was made in light of the federal statutory scheme regulating generic drugs—The Drug Price Competition and Patent Term Restoration Act of 1984, Pub L. No. 98-417, 98 Stat. 1585—which requires parties to reasonably cooperate in expediting the resolution of this type of patent infringement litigation. Respondent asserts that, by virtue of other provisions of that statutory scheme, such an interim settlement delayed respondent from entering the market and therefore violated Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. 1, 2.

The questions presented are:

1. Whether the interim settlement inflicted antitrust injury on respondent.

2. Whether respondent has antitrust standing to challenge the interim settlement.

3. Whether, under the *Noerr-Pennington* doctrine and the doctrine of *Standard Oil Co. (Indiana) v. United States*, a bona fide settlement of a patent infringement claim can give rise to antitrust liability.

## PARTIES TO THE PROCEEDING

All parties appear in the caption of this case.

Petitioner Andrx Pharmaceuticals, Inc. is a wholly-owned subsidiary of Andrx Corporation. Andrx Corporation is a publicly traded company.

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The opinion of the court of appeals (Pet. App. 1a-34a) is reported at 256 F.3d 799. The opinion of the district court (Pet. App. 35a-49a) is reported at 83 F. Supp.2d 179.

## JURISDICTION

The judgment of the court of appeals was entered on July 31, 2001. Pet. App. 1a. A timely petition for rehearing was denied on September 14, 2001. Pet. App. 50a-51a. On December 4, 2001, the Chief Justice extended the time in which to file a petition for a writ of certiorari to and including January 12, 2002. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

## STATUTES AND REGULATIONS INVOLVED

Pertinent portions of The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), are reproduced at Pet. App. 52a-64a. Pertinent portions of 35 U.S.C. 282 & 284 are reproduced at Pet. App. 64a-66a. The 1997 version of 21 CFR 314.107 is reproduced at Pet. App. 67a-74a.

## STATEMENT

1. "Generic" drugs are drug products that are "bio-equivalent" to previously-developed brand-name drugs—i.e., their biological effect when administered is identical to that of the brand-name product. Because generic drug manufacturers do not incur all the costs of developing the drug, generic drugs can generally be sold for significantly less than their brand-name "pioneer" counterpart drugs. See *United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 & n.1 (1983). The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984)—commonly known as the "Hatch-Waxman Act"—sought to provide a means by which generic drugs could be

made available to consumers more quickly without undercutting the patent rights of pioneer drug manufacturers. See generally *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 675-77 (1990).

In order to obtain approval from the Food and Drug Administration to market its drug, a pioneer drug manufacturer must complete a New Drug Application (NDA). See 21 USC 355(a). Once the NDA has been approved, the Hatch-Waxman Act provides that the manufacturer of a bioequivalent generic drug need not file another NDA but may instead file an Abbreviated New Drug Application (ANDA) that relies in part on the safety and efficacy studies of the NDA. The ANDA procedure is accordingly faster than the NDA procedure, although approval of an ANDA takes two or more years and is far from guaranteed. See 21 U.S.C. 355 (j)(2)(A); *Eli Lilly*, 496 U.S. at 676.

If the pioneer drug is claimed by one or more unexpired patents, the ANDA must contain a "certification" concerning the patents. See 21 U.S.C. 355(j)(2)(A)(vii). The type of certification relevant to this action is known as a "Paragraph IV" certification in which the ANDA applicant certifies its position that its generic drug will not infringe the patents or that the patents are invalid and unenforceable. See 21 U.S.C. 355(j)(2)(A)(vii)(IV). If the ANDA contains a Paragraph IV certification, the Hatch-Waxman Act provides a 45-day period in which the pioneer drug patent holder may bring a patent infringement action against the applicant based on the filing of the ANDA as the infringing event. 35 U.S.C. 271(e)(2); 21 U.S.C. 355(j)(5)(B)(iii).

Patent infringement suits against proposed generics are governed by the provisions of the Hatch-Waxman Act. If the patent holder brings such a suit, "each of the parties shall reasonably cooperate in expediting the action". 21 U.S.C. 355 (j)(5)(B)(iii). The Hatch-Waxman Act also emphasizes the importance Congress placed on respecting the intellectual

property rights of the pioneer drug manufacturer by barring the FDA from granting final approval to the ANDA (even if the ANDA otherwise satisfies all FDA health and safety requirements) for thirty months or until the patent infringement issue is resolved, whichever occurs first. *Ibid.*

The Hatch-Waxman Act rewards the first ANDA applicant by providing a period of 180 days in which it has the exclusive right to market its product. The FDA may not approve other subsequently filed ANDAs for the same pioneer drug product during that period. 21 U.S.C. 355(j)(5)(B)(iv). This 180-day exclusivity period provides an incentive to companies to be the first to develop a generic product despite the time and resources that will be spent defending patent litigation, and prevents other generic manufacturers from free-riding on the first applicant's effort. After that 180-day period, other manufacturers can, upon approval of their ANDAs, compete with the first ANDA applicant (and with the pioneer drug). The Hatch-Waxman Act specifies that the 180-day period begins to run when the first of two events occurs: when a court finds the patent invalid or not infringed; or when the ANDA applicant actually begins to market the drug. 21 U.S.C. 355(j)(5)(B)(iv)(II). Until July 1998, the FDA, by regulation, imposed another requirement: the first generic manufacturer could not obtain the benefit of the 180-day period of exclusivity unless it had "successfully defended against a suit for patent infringement" before a subsequent ANDA filer was eligible for final FDA approval. 21 C.F.R. 314.107(c)(1) (1997); Abbreviated New Drug Application Regulations: Patent and Exclusivity Provisions, 59 Fed. Reg. 50,338, 50,353 (October 3, 1994) (Pet. App. 98a).

If the generic manufacturer receives final approval from the FDA prior to the conclusion of the patent litigation, it is entitled to await the conclusion of the patent litigation before launching its product. If the generic drug is subsequently found to have infringed the pioneer drug's patent, the generic

manufacturer will be liable for damages measured not by the generic company's profits but rather by the pioneer manufacturer's lost profits, and such damages could be trebled. 35 U.S.C. 284; *Stickle v. Heublein, Inc.*, 716 F.2d 1550, 1560-61 (Fed. Cir. 1983). Because each sale of the generic product takes the place of a sale of the more expensive pioneer drug, the pioneer manufacturer's lost profits necessarily will significantly exceed the profits earned by the generic manufacturer even before trebling.

The FDA itself has repeatedly acknowledged that, given the significant risks of launching during on-going patent litigation, it expects that a "prudent" applicant will wait to resolve patent infringement claims before marketing its product:

> It serves the public interest to permit a prudent ANDA holder in that situation to stay off the market until the litigation is resolved, thereby minimizing potential damages.

FDA Proposed Rules: Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,894 (July 10, 1989) (Pet. App. 115a). Indeed, the FDA has expressly recognized that an interpretation of the statute that would require a first applicant to market its product before resolving the patent claims in order to retain its exclusivity could wholly eliminate the value of the statutory grant of exclusivity to the first generic applicant.

> Beginning the 180-day exclusivity period before the resolution of the appeals process would render the exclusivity valueless to a prudent applicant who delayed marketing until the issues were resolved on appeal.

59 Fed. Reg. 50,338, 50,352 (October 3, 1994)(Pet. App. 93a-94a); accord *id.* at 50,355 (Pet. App. 103a).

2. In 1995, petitioner Andrx Pharmaceuticals, Inc. (Andrx) filed an ANDA seeking permission to market a generic form of Cardizem CD, a drug that is widely prescribed for the

treatment of angina and hypertension. Cardizem CD was at that time being marketed by Hoechst Marion Roussel, Inc. (HMRI), now known as Aventis Pharmaceuticals, Inc., which also holds the patents that it claimed covered Cardizem CD. These patents are presumed to be valid. 35 U.S.C. 282. As part of its ANDA, Andrx made a Paragraph IV certification with respect to all the patents that claimed Cardizem CD. In January 1996, within the 45-day period provided by Hatch-Waxman, HMRI sued Andrx for patent infringement in the United States District Court for the Southern District of Florida. Pet. App. 40a, 5a.

In accordance with the statutory directive, both HMRI and Andrx tried to expedite the patent litigation. Both HMRI and Andrx filed potentially dispositive motions, but the district court held no hearings, issued no rulings, and refused the parties' repeated requests for argument or a trial. See Docket Sheet for *Hoechst Marion Roussel, Inc. v. Andrx Pharmaceuticals, Inc.*, 96 Civ. No. 06121 (S.D. Fla.). In September 1997, the FDA tentatively approved Andrx's ANDA—tentative because the patent litigation was still pending in the district court and thirty months had not yet elapsed. See Pet. App. 40a, 6a. Given the lack of activity from the Court, HMRI informed Andrx that it was considering seeking a preliminary injunction that would restrain Andrx from marketing generic Cardizem CD as soon as the thirty-month period expired. Pet. App. 133a.

A decision by Andrx to begin marketing its generic version of Cardizem CD before the conclusion of the patent infringement litigation would have created serious risks for both Andrx and HMRI. If Andrx had been enjoined from marketing its generic product during the pendency of the patent litigation, this could have been considered a court decision sufficient to trigger the 180-day exclusivity period with regard to Andrx even though Andrx would have been enjoined from actually marketing during that period. If

Andrx had not been enjoined by the Court from marketing its generic product during the course of the litigation, Andrx's generic drug would have dramatically lowered HMRI's revenues and profits from the pioneer drug. If Andrx subsequently prevailed in the patent infringement litigation, it would have profited greatly. But if Andrx marketed its product and subsequently lost the patent litigation, the damages award would, in all likelihood, have bankrupted Andrx, and HMRI would have been unable to recover for the damages suffered by the marketing of an infringing product.

In these circumstances, HMRI and Andrx—both faced with litigation-related uncertainty and risk—took steps to cooperate to expedite the litigation as the Hatch-Waxman Act directed them to do. See 21 U.S.C. 355(j)(5)(B)(iii)(III). In particular, they agreed to a Stipulation and Agreement that constituted an interim settlement of HMRI's threatened motion for a preliminary injunction. That Stipulation is the subject of this case.[1] Under the terms of the Stipulation, HMRI agreed not to pursue a preliminary injunction against an Andrx launch of its generic product. HMRI also agreed that, if it prevailed in the patent infringement litigation, it would issue a non-exclusive license to Andrx, in exchange for a specified payment. It further agreed to license Andrx on an interim basis if the litigation lasted beyond 1999. Pet. App. 134a, 137a-140a.

Andrx agreed to maintain the status quo by not marketing its generic versions of Cardizem for as long as the Stipulation remained in effect, namely while the patent infringement litigation was pending. HMRI agreed that if Andrx ultimately prevailed in the patent litigation, it would pay Andrx $100 million per year from the time Andrx received FDA approval, an amount that was stipulated by the parties to represent the profits Andrx could have made had the patent litigation ended

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[1] The text of the Stipulation and Agreement is set forth at Pet. App. 132a-147a.

and had Andrx prudently been able to market its generic product during that time. Pet. App. 135a. In the interim, HMR agreed to pay $10 million per quarter year to Andrx until the patent litigation was resolved; those payments were to be credited against the $100 million per year if Andrx prevailed and were to be used to purchase the license if Andrx lost the patent litigation. The payments were to begin when Andrx's ANDA was approved (no sooner than thirty months after notice was received of the Paragraph IV certification) and terminate at the end of the patent litigation, or if the litigation lasted past December 1999, when Andrx exercised its option to license the patent. Pet. App. 136a-137a. If Andrx lost the patent litigation, or the patent litigation continued beyond December 1999, then Andrx would be entitled to obtain a license to market its generic product using the money received from the interim payments for the license. Pet. App. 137a-140a. If the district court in the patent litigation had resolved the patent litigation before the end of the 30-month period, no payments would have occurred.

The Stipulation also contained other provisions designed to ensure that the Hatch-Waxman structure was not manipulated. For example, the Stipulation defined Andrx's product broadly, so that Andrx would be free to continue to try to modify its generic version of Cardizem without having HMRI claim that every modification triggered a new 30-month period. See Pet. App. 132a. Similarly, the Stipulation contained a provision designed to prevent HMRI from amending its labeling without notice to Andrx (Pet. App. 135a), a tactic commonly employed by pioneer drug manufacturers to force a generic manufacturer to amend its ANDA to conform to the new labeling, thus further delaying FDA approval and marketing of the generic product. See, e.g., Naomi Aoki, *Drugmakers Poised for Battle Brand Name Firms Up Stakes In Face of Generic Competition*, Boston Globe, November

26, 2001, at D1. Also, consistent with its own desire to market its generic product as soon as possible, Andrx agreed to continue to prosecute its ANDA, so that HMRI could be assured a definitive resolution of the patent issues and generic entry could be hastened. Pet. App. 134a.

Through the Stipulation, HMRI and Andrx cooperated to expedite the termination of that litigation by maintaining the status quo in the patent litigation and avoiding prolonged litigation concerning a preliminary injunction. The district court, though, continued to take no action on any pending motions in the patent litigation. Meanwhile during the pendency of the patent litigation, Andrx sought and received FDA approval for a reformulated generic version of Cardizem CD that HMRI acknowledged did not infringe any patent. HMRI and Andrx thereafter settled the patent litigation by HMRI agreeing not to bring an action claiming that the reformulated product infringed its patents so long as that product met certain specifications, and Andrx agreed not to sell the original formulation. Pet. App. 7a. Upon settlement of the patent litigation, the Stipulation terminated pursuant to its terms. Andrx then started to sell its reformulated product, and the 180-day exclusivity period began. *Ibid.*

3. In January 1998, four months after the Stipulation was entered, Andrx filed suit against the FDA challenging the "successful defense" regulation as it might be applied to two ANDAs Andrx had filed. Andrx also named as defendants three firms, including Biovail, that had filed ANDAs after Andrx for the same products. With respect to both ANDAs, the FDA had taken the position that Andrx was not entitled to the 180-day exclusivity period because HMRI's patent litigation against Andrx was still pending, and if any of the subsequently filed ANDAs were eligible for final approval that approval would not be withheld regardless of Andrx's position as the first filer on both of the ANDAs. Pet. App. 38a-39a. Andrx's suit asserted that the "successful defense"

regulation was invalid because it was not consistent with the statute. 21 U.S.C. 355 (j)(5)(B)(iii). After Andrx filed its action, in April 1998, the District of Columbia Circuit invalidated the "successful defense" regulation. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. 1998). It was not until July 1998, long after the Stipulation was executed, that the FDA announced it would no longer enforce that regulation. Pet. App. 7a n.6; see also Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability, 63 Fed. Reg. 37,890 (July 14, 1998)(Pet. App. 81a-83a). As a result, Andrx's action against the FDA and the other ANDA filers became moot. Pet. App. 39a.

In the meantime, Biovail counterclaimed against Andrx, alleging that the Stipulation threatened to prevent Biovail from marketing its generic version of Cardizem and thereby violated Sections 1 and 2 of the Sherman Antitrust Act, 15 U.S.C. 1, 2.[2] The United States District Court for the District of Columbia dismissed Biovail's counterclaim on the ground that Biovail "has not established the existence of antitrust standing." Pet. App. 43a. Assuming Biovail's allegations to be true, as is required in a motion to dismiss, the district court ruled first that Biovail had not established "antitrust injury"—a prerequisite for suing under the antitrust laws—for two independent reasons. First, Biovail had not pled that its ANDA for its generic version of Cardizem had been approved; therefore Biovail could not have marketed its product irrespective of anything Andrx did. Pet. App. 44a.

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[2] Biovail also failed counterclaims under state law. The district court dismissed those claims without prejudice, and Biovail did not appeal. See Pet. App. 44a. The district court had jurisdiction over the federal counterclaims by virtue of 28 U.S.C. 1331 and 28 U.S.C. 1337.

Second, the district court explained, the source of any injury to Biovail was not a violation of the antitrust laws but rather the operation of the Hatch-Waxman Act:

> Andrx is free to wait until the conclusion of the Florida litigation before it begins to market its generic, and indeed the statute contemplates that possibility. Under these circumstances, no generic Cardizem manufacturer could market its product until 180 days from the conclusion of the litigation, an eventuality perfectly within the scheme set forth by the Hatch-Waxman Amendments.

Pet. App. 44a. The district court concluded that Biovail's alleged injury could not have flowed from Andrx's alleged wrongdoing: "The reason Biovail cannot enter the market is because of the existence of a troublesome statutory scheme that prohibits it from marketing a drug until the first ANDA recipient goes to market, and which places no restrictions on when, or even whether, that applicant must go to market." Pet. App. 45a.

The district court also ruled that Biovail lacked antitrust standing because of the speculative nature of the harm it suffered; the court explained that "[t]he primary injury alleged here by Biovail—delay in sales—is speculative because there is no evidence that absent the Andrx-HMRI agreement, Biovail would be marketing its generic drug." Pet. App. 47a. The district court further noted that consumers of Cardizem were "clearly * * * more direct victims of Andrx's alleged violation" and that because there were other antitrust actions pending against Andrx that challenged the Stipulation, "[t]here also is the potential here for duplicative recoveries and inconsistent holdings." Pet. App. 48a, 49a. Those factors, too, counseled against antitrust standing.

4. The court of appeals reversed and remanded the case to the district court for further proceedings. Pet. App. 34a. The court of appeals rejected Andrx's argument and overturned

the holding of the district court that even if Biovail amended its complaint, Biovail's complaint should still be dismissed for, among other things, lack of antitrust injury and lack of antitrust standing. Pet. App. 22a-27a. The court of appeals instead ruled that the district court should have dismissed the counterclaim without prejudice, in order to give Biovail an opportunity to amend its pleadings to allege that its ANDA had been approved and that it was prepared to go to market. *Ibid.*

In particular, the court of appeals disagreed with the district court's conclusion that any injury to Biovail was caused by the Hatch-Waxman statutory scheme, not by any antitrust violation. Pet. App. 15a. The court of appeals also rejected the district court's conclusions that consumers were more directly injured than Biovail by any alleged antitrust violation; that there was a danger of duplicative recovery; that Biovail's damages were speculative; and that Biovail's attack on the Stipulation was barred by the *Noerr-Pennington* doctrine. See *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers of America v. Pennington*, 381 U.S. 657, 669-72 (1965). Pet. App. 27a-34a.

## REASONS FOR GRANTING THE PETITION

The court of appeals' decision is inconsistent with the decisions of this Court and rests on a grievous misunderstanding of the relationship between the Hatch-Waxman Act and the antitrust laws. The court of appeals wrongly concluded that Biovail had alleged antitrust injury; wrongly concluded that Biovail had antitrust standing to challenge the Stipulation; and misapplied or ignored well-established doctrines that give parties the right to initiate and settle bona fide litigation, including litigation to defend intellectual property rights, without incurring antitrust liability. Not surprisingly, the decisions of courts of appeals in several

other circuits—the Second, Third, Sixth, and Seventh Circuits, at the least—demonstrate that those courts would have rejected Biovail's claim in this case.

Further, the court of appeal's decision in this high-profile case will have highly damaging repercussions. The Stipulation was an interim settlement of litigation between Andrx and HMRI—a fact that the court below all but ignored. The court of appeals' ruling that this settlement can give rise to treble damages under the antitrust laws will make settlements vastly less likely in the Hatch-Waxman Act context. The result will be, inevitably, to discourage the development of generic drugs—at a time when the rising cost of pharmaceuticals is a matter of increasing public concern—thus defeating the express purpose of the Hatch-Waxman Act.

The settlement in this case was widely noted. The FDA cited concerns about arrangements such as the Stipulation in connection with proposed revisions to the regulations governing exclusivity. See FDA Proposed Rule Regarding 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,874-75 (Aug. 6, 1999)(Pet. App. 79a-80a). The settlement was also the subject of a Federal Trade Commission proceeding culminating in a prospective consent order. The FTC found no "delay in the entry into the market of a generic version of Cardizem CD by Andrx or any potential manufacturer" including Biovail, and no delay in "consumer access to a generic version of Cardizem CD." Pet. App. 126a. This specific litigation, and the Stipulation, have been the subject of extensive commentary in professional journals.[3]

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[3] See Mary L. Azcuenaga, *Recent Issues In Antitrust And Intellectual Property*, 7(1) B.U.J. Sci. & Tech. L. 1 (2001); Robert E. Bloch, et al., *Settlement of Patent Disputes: Antitrust and Intellectual Property at the Crossroads*, Antitrust Report, Nov. 2001, at 2; Janusz A. Ordover, *Settling Patent Disputes*, Fall Forum: New Technologies/New Administrations (American Bar Association Section of Antitrust Law),

This litigation has attracted this degree of attention because the dilemma that Andrx confronted, and that prompted it to enter the Stipulation, will confront generic drug manufacturers repeatedly in the future. If a company in Andrx's position cannot reach an interim settlement agreement without facing antitrust litigation from a disgruntled competitor, it will be forced to choose between marketing the generic drug—thus risking the possibility of bankruptcy, potentially undermining the legitimate rights of the patent holder, and potentially losing its 180-day exclusivity—or enduring prolonged litigation that denies it the return on its investment for as long as the patent litigation endures. The prospect of being in this position will unquestionably deter firms from seeking to develop generic drugs in the first place, to the detriment of consumers and in direct contravention of Congress's purposes in enacting the Hatch-Waxman Act.

Andrx resolved this dilemma by entering into an interim settlement agreement that allowed both parties to deal with the risks and burdens of litigation. Andrx agreed to maintain the status quo in return for the right to license HMRI's patents–thus ensuring that a generic product would come to market regardless of the outcome of the patent litigation – and for the funds needed to defray the cost of the litigation, the research to reformulate its product, and (if it lost the litigation) the cost of a license.

The court of appeals' decision in this much-watched case threatens to foreclose the possibility of such beneficial, procompetitive settlements and to place manufacturers of generic drugs back in the destructive dilemma that the Stipulation avoided. The court of appeals' ruling is

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November 15-15, 2001, at 498; Yee Wah Chin and Thomas G. Krattenmaker, *Antitrust Update*, Mergers and Acquisitions, December 2001, at 30; John F. Resek, *Biovail v. Hoechst Aktiengesellshaft, Inc: An Analysis Under The Sherman Act And The Noerr-Pennington Doctrine*, 10 Fordham Intell. Prop. Media & Entertainment L.J. 571 (2000).

interlocutory, but the court rejected several arguments that Andrx made in defense of the Stipulation and in other respects failed to adhere to settled Supreme Court precedent. Other generic drug manufacturers are now on notice that if they enter an interim settlement comparable to Andrx's, they can be subject to an antitrust suit brought by a competitor.

This result is certain to have a chilling effect on settlements and, therefore, on incentives to innovate, in precisely the area where Congress has sought to promote innovation by adopting the Hatch-Waxman Act. A manifestly erroneous decision that has such damaging practical consequences for an important federal regulatory scheme—and that is inconsistent with the decisions of other courts of appeals as well as the decisions of this Court—warrants further review.

## I. THE STIPULATION DID NOT INFLICT ANTITRUST INJURY ON BIOVAIL

Biovail's complaint plainly did not establish that Biovail suffered antitrust injury from the Stipulation, and the court of appeals' contrary ruling is wrong. As this Court has explained, a plaintiff in an antitrust action must show more than injury causally related to the act that allegedly violated the antitrust laws. "Plaintiffs must prove *antitrust* injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (emphasis in original); see also *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990); *Cargill, Inc., v. Monfort of Colorado, Inc.*, 479 U.S. 104, 109-10 (1986); *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 539-40 (1983).

The claim that the Stipulation caused Biovail antitrust injury is implausible on its face. The Stipulation provided that Andrx would not begin marketing its generic product.

Biovail and Andrx are competitors; they both manufacture generic versions of Cardizem. A firm is benefited, not harmed, when a potential competitor decides not to enter a market. Andrx's promise to keep its product off the market, in and of itself, could not possibly have inflicted antitrust injury on Biovail. See *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 583 (1986).

The court of appeals appears simply to have ignored the fact that the central feature of the Stipulation was, if anything, favorable to Andrx's competitor Biovail were it not for the regulatory scheme of the Hatch-Waxman Act. Instead, the court of appeals treated the Stipulation as an agreement by Andrx to "exclude other competitors from entering the market." Pet. App. 18a. But this notion—that the Stipulation inflicted antitrust injury on Biovail by keeping it out of the market—is unsustainable, for several reasons.

A. First, the Stipulation did not keep Biovail out of the market—either at the time the Stipulation was entered or afterwards. The court of appeals' conclusion that the Stipulation inflicted antitrust injury on Biovail depended entirely on what the court characterized as "Andrx's commitment not to trigger the running of the 180-day exclusivity period" and "Andrx's pledge . . . to forestall other applicants from receiving final FDA approval." Pet. App. 18a, 20a. But Andrx could not have made any such "commitment" or "pledge" when it entered the Stipulation, because under the regulations then applicable Andrx itself had no right to the exclusivity period.

Under FDA regulations in force at the time of the Stipulation, no ANDA applicant (such as Andrx) could take advantage of the 180-day exclusivity period until it had "successfully defended" a patent infringement action. 21 C.F.R. 314.107(c)(1) (1997). Until that point, the FDA would not withhold approval of any other eligible ANDA. At the time the Stipulation was signed, Andrx, of course, had not

successfully defended the patent infringement action. By its own terms, the Stipulation would expire whenever that action was concluded. In other words, the Stipulation would never be in effect at a time when Andrx's ANDA would preclude FDA approval of any other ANDAs. Thus, in entering into the Stipulation, Andrx could not possibly have been agreeing to keep Biovail or anyone else out of the market; under governing law, Andrx did not have the power to do so.

The court of appeals rejected this straightforward argument on the ground that the "successful defense" regulation was ultimately invalidated before, in the court of appeals' words, the Stipulation went "into effect * * * in July 1998." Pet. App. 19a. This is sleight of hand. In July 1998, Andrx's ANDA was approved and Andrx became eligible for a payment under the Stipulation. But the Stipulation became binding when it was entered, in September 1997. If there was an agreement that inflicted antitrust injury on Biovail, it occurred at that point—when the Stipulation was entered. At that point, the "successful defense" regulation was—indisputably—still being enforced by the FDA. In fact, that regulation had not been declared unlawful by any court of appeals; district court decisions on the validity of the regulation were divided. Compare *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir. 1998), with *Granutec, Inc. v. Shalala*, 1997 WL 1403894 (E.D.N.C. July 3, 1997), *rev'd*, 139 F.3d 889 (4th Cir. 1998). The FDA explained that even in the period after the Stipulation was signed, namely late 1997 and early 1998, it remained FDA "policy . . . to apply the 180-day exclusivity provisions of the statute as set forth in [the successful defense regulation] to all [generic drug applications] to which the regulation would, on its face, apply, whether they were submitted before or after the Mova decision." FDA Policy Clarification, 62 Fed. Reg. 63,268 (November 28, 1997)(Pet. App. 85a-86a). This remained the FDA position until July 1998. The FTC, after an exhaustive

investigation which found that the Stipulation did not delay the entry of any generic product, stated unequivocally about the "successful defense" regulation: "At the time [HMRI and Andrx] entered into the [Stipulation] in 1997, the governing FDA regulations required that an ANDA applicant successfully defend the patent holder's parent suit in order to be entitled to this exclusivity." Pet. App. 123a.

The court of appeals' treatment of the "successful defense" regulation conflicts with the principle, recognized in other circuits, that for antitrust purposes an agreement is to be judged as of the time it is made, not in light of subsequent developments. See, e.g., *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985) ("A court must ask whether an agreement promoted enterprise and productivity at the time it was adopted."). Indeed, the Second Circuit has ruled that even a *foreseeable* change in circumstances cannot justify the imposition of antitrust liability for an agreement that was not anticompetitive when entered. See *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1208-10 (2d Cir. 1981). The Second Circuit held in that case that to attempt to impose antitrust liability for a foreseeable change in circumstance that did not exist when an agreement was executed "would severely trample upon the incentives provided by our patent laws and thus undermine the entire patent system." *Ibid.* Here too, allowing the Stipulation to be judged by subsequent changes to its enforcement by the FDA would trample upon the incentives provided by the Hatch-Waxman Act and undermine its regulatory purpose.

Application of the antitrust laws based on changes in the competitive environment resulting from *ex post facto* reversals in regulatory policy also raises due process concerns. See *Landgraf v. USI Film Products*, 511 U.S. 244, 270-71 (1994)(presumption against retroactive application of new law applies with special force to existing contracts due to

importance of "predictability and stability"); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988) (presumption against retroactivity applies to administrative rules).

B. 1. Even after the FDA determined not to enforce the "successful defense" regulation, Andrx did not have the ability to keep Biovail out of the market. As we have noted, the Hatch-Waxman Act provides that the 180-day exclusivity period will begin on "the date of a decision of a court * * * holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. 355(j)(5)(B)(iv)(II). This provision is not limited to the court that is hearing the patent infringement action against the first ANDA applicant. *Teva Pharms., USA, Inc., v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999). Specifically, a decision in a case involving a subsequent ANDA applicant can also start the running of the 180-day exclusivity period for the first applicant. *Ibid.*

Biovail, therefore, could have filed a declaratory judgment action against HRMI, seeking a declaration that its generic version of Cardizem did not infringe any patent. The Hatch-Waxman Act specifically contemplates such actions. See 21 U.S.C. 355(j)(5)(B)(iii)(III). If Biovail had prevailed in such a declaratory judgment action, Andrx's 180-day exclusivity period would have begun to run immediately. After that period elapsed, Biovail would have been free to market its product, as soon as the FDA approved its ANDA. Thus if Biovail brought and won a declaratory judgment action against HMRI, Andrx would have been powerless to prevent Biovail from marketing its product. For this reason, as well, the Stipulation cannot possibly be read as containing what the court below called a "commitment" or "pledge" by Andrx to exclude Biovail.

The court of appeals' only response to this point was that "the time involved to obtain [a declaratory] judgment made this option less than 'fully available' " to Biovail. Pet. App. 21a (citation omitted). But the court of appeals

in making this determination ignored that Biovail had specifically alleged that HMRI could not sue Biovail for patent infringement because, in order to accelerate Biovail's generic entry, the FTC insisted that HMRI relinquish the right to do so. Biovail's Answer and Counterclaims ¶ 37. This circumstance would have ensured Biovail a quick judgment had Biovail moved for a declaratory judgment akin to that obtained in *Teva*. In any case, though, the question is not whether Biovail could have entered the market costlessly; the question is whether Andrx excluded Biovail. The barrier to Biovail's entry—on the court of appeals' own reasoning—was not Andrx's action but simply the fact that, before Biovail could enter the market, it had to spend the time and resources needed to vindicate its claims of noninfringement. This cannot constitute antitrust injury. Nothing in the antitrust laws gives a firm the right to costless and delay-free litigation—much less the right to free-ride on a competitor's litigation, as the court of appeals, apparently, thought Biovail was entitled to do with Andrx.

The court of appeals' ruling on this point is also, not surprisingly, inconsistent with decisions in other circuits. In *CBS v. ASCAP*, 620 F.2d 930 (2d Cir. 1980), the Second Circuit ruled that even an arrangement that might otherwise constitute price fixing would be lawful if the purchaser had "realistically available marketing alternatives." *Id.* at 935; see *id.* at 936. While the Second Circuit remarked that "[a]n antitrust plaintiff is not obliged to pursue any imaginable alternative, regardless of cost or efficiency" (*ibid.*), it specifically rejected the argument that an alternative is not available just because "it would take some amount of time and money" to employ it. *Id.* at 937. "[A plaintiff] cannot expect the antitrust laws to assure it that [its objective] can be accomplished instantly or at no expense." *Ibid.* That is exactly what, according to the court below, Biovail was entitled to expect. The routine burdens of litigating to

vindicate its own intellectual property claims cannot constitute, in the Second Circuit's words, "a barrier of which [Biovail] can complain". *Ibid.*

2. Biovail had another way to attempt to enter the market. FDA regulations provide that if the first ANDA applicant "is not actively pursuing approval of its abbreviated application, FDA will make approval of subsequent [ANDAs] immediately effective if they are otherwise eligible". 21 C.F.R. 314.107(c)(3). If Biovail believed that Andrx was abusing the Hatch-Waxman process in order to exclude Biovail from the market, Biovail could have tried to persuade the FDA to extend its regulation to cover Andrx's conduct and gain immediate approval. The court of appeals asserted that this avenue was not available to Biovail because Andrx maintained its ANDA. See Pet. App. 21a. Biovail, however, never even sought to pursue this avenue of relief. Having not even petitioned the FDA for relief that was a sine qua non of entering the market, Biovail cannot complain that Andrx's conduct excluded it.

C. Finally, even if, contrary to fact, the Stipulation prevented Biovail from entering the market, it does not follow that Biovail has stated a violation of the antitrust laws. Even a restraint on competition is lawful if it is ancillary to a legitimate cooperative agreement. See, e.g., *NCAA v. Board of Regents of Univ. of Oklahoma*, 468 U.S. 85, 101-03 (1984). The Stipulation was an interim settlement of a patent dispute between HMRI and Andrx. Any effects on others, including Biovail, were an incidental byproduct of the Stipulation, brought about by the Hatch-Waxman Act's limitation on the rights of subsequent ANDA applicants.

The focus of the Stipulation was, of course, not Biovail; it was the relationship between Andrx's product and HMRI's patents. The Stipulation was highly procompetitive, not least because it guaranteed Andrx a license even if Andrx ultimately lost the patent infringement case. To allow the

incidental effects of such a settlement on a third party to constitute actionable antitrust injury would defeat the purposes of the antitrust laws.

The court of appeals' response to this point was to acknowledge the possibility that the central agreement between Andrx and HMRI might have been lawful, but to assert that Andrx's "commitment to continue to prosecute its ANDA" could have constituted an unlawful agreement. Pet. App. 26a. This assertion by the court of appeals—seizing on the provision of the Stipulation in which Andrx agreed that it would "diligently prosecute the ANDA for the Andrx Product" (Pet. App. 134a)—is contrived and implausible. Biovail did not allege that Andrx would have dropped its ANDA had it not entered the Stipulation. Nor is it remotely plausible to suppose that Andrx would have done so: Andrx continued to innovate, and eventually reformulated its product in a way that clearly did not infringe the HMRI patent. There is no indication that Andrx ever contemplated abandoning its ANDA.

In any event, the provision of the Stipulation in which Andrx agreed not to abandon its ANDA is a particularly clear example of an ancillary provision. It was reasonable for HMRI to insist on protection against the possibility that Andrx, having entered the interim settlement and obtained compensation for potential lost profits, would moot the case before the issues concerning HMRI's patents were resolved. In that way Andrx's commitment to prosecute the ANDA made it possible for Andrx and HMRI to enter the overall interim settlement, which had decidedly procompetitive effects. That is the hallmark of an ancillary condition.

D. The courts of appeals in several circuits—which, unlike the District of Columbia Circuit, enforce this Court's requirement of antitrust injury with appropriate rigor—would, without question, have rejected Biovail's claim because Biovail's alleged injuries did not flow from that which may

arguably have made the Stipulation illegal. *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 487-88 (1977) (Clayton Act §4 plaintiff must allege injury that "flows from that which makes defendants' acts unlawful"). The Court in *Brunswick* determined then when plaintiffs "would have suffered the identical 'loss' but no compensable injury" through lawful activity as was caused by the allegedly anticompetitive conduct, then plaintiffs' "injury was not of 'the type that the statute was intended to forestall'". *Ibid.*

The *Brunswick* analysis has been used by many circuit courts to reject most competitor standing cases including those similar to this one. For example, in *Hodges v. WSM, Inc.*, 26 F.3d 36 (6th Cir. 1994), the plaintiff, who operated a shuttle bus service, asserted that the defendants had participated in an illegal market division conspiracy, in which certain other firms agreed not to provide shuttle bus service to Opryland, U.S.A., an amusement and tourist attraction. The plaintiff alleged that "the defendants * * * policed the agreement by refusing entry onto Opryland property to all remaining shuttle service companies, including plaintiffs'." *Id.* at 37. Even though the plaintiff had alleged a direct, but-for connection between the illegal agreement and its injury, the Sixth Circuit ruled that the plaintiff had failed to allege antitrust injury: "Because plaintiffs did not allege * * * that the illegal antitrust conduct was a necessary predicate to their injury or that defendants could exclude plaintiffs only by engaging in the antitrust violation, it was appropriate to dismiss the case pursuant to Federal Rule of Civil Procedure 12(b)(6)." 26 F.3d at 39. The Sixth Circuit has repeatedly taken this approach. See, e.g., *Valley Prods. Co. v. Landmark*, 128 F.3d 398, 404 (6th Cir. 1997); *Axis, S.p.A. v. Micafil, Inc.*, 870 F.2d 1105, 1112, (6th Cir. 1989).

Similarly, the Third Circuit, in a series of cases dealing with competition within a regulated industry, has emphasized that an antitrust plaintiff cannot recover for injuries that were the result of the regulatory scheme. This is true even if the

defendant's conduct was anticompetitive and might have caused the injury in the absence of regulation. As the Third Circuit explained: "The presence of the regulatory scheme and need for [regulatory] approval * * * cuts the causal chain and converts what might have been deemed antitrust injury in a free market into only a speculative exercise." *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 267-68 (3d Cir. 1998). See also *Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417-18 (3d Cir. 1997); accord *Lucas Auto. Eng'g, Inc. v. Bridgestone/ Firestone, Inc.*, 140 F.3d 1228, 1234-35 (9th Cir. 1998) (no antitrust standing to allege antitrust violation where same alleged loss would have resulted from lawful acquisition as from alleged anticompetitive acquisition); *ES Dev., Inc. v. RWM Enters., Inc.*, 939 F.2d 547, 553 (8th Cir. 1991).

Here, Biovail's supposed injury is, as the district court ruled, entirely attributable to the Hatch-Waxman regulatory scheme; were it not for the Hatch-Waxman 180-day exclusivity period, Biovail would unquestionably have been free to enter the market at any time. In fact without the Hatch-Waxman Act, Biovail would only have been helped by an agreement by a competitor to not market a product. In any case, Biovail would have suffered the same injury had Andrx exercised its right under the Hatch-Waxman Act not to market its generic product. Both Congress and the FDA have recognized that awaiting the end of patent litigation before marketing is a prudent practice. Indeed a main purpose of the Hatch-Waxman Act was to give the generic drug manufacturer control over when to launch its product so it could benefit from the 180-day grant of exclusivity. Assuming that Andrx could have excluded Biovail from the market at all, Biovail, like the plaintiff in *Hodges*, unquestionably cannot allege that Andrx "could exclude [it] only by engaging in the antitrust violation." 26 F.3d at 39. Biovail's alleged injury (if any), therefore, cannot flow from that which makes the purported anticompetitive activity illegal. Additionally, as

explained above, even after the Stipulation Biovail was only excluded (if it was excluded at all) by the FDA's 1998 decision under the Hatch-Waxman Act to not enforce the "successful defense" regulation.

Finally, in *O.K. Sand & Gravel, Inc. v. Martin Marietta Technologies, Inc.*, 36 F.3d 565 (7th Cir. 1994), the antitrust plaintiff alleged—much as Biovail does here—that injury to it was a necessary concomitant of an illegal agreement between the defendant and a competitor. See *id.* at 573-74. The Seventh Circuit rejected the claim, carefully making the distinction that the court below did not make—between injury that was a "necessary prerequisite" of the allegedly illegal agreement and antitrust injury caused by the illegal agreement. *Ibid.* The Seventh Circuit has further stated that antitrust plaintiffs must be able to "exclude the possibility that the defendant's conduct was as consistent with competition as with illegal conduct." *Indiana Grocery, Inc. v. Super Valu Stores, Inc.*, 864 F.2d 1409, 1413 (7th Cir. 1989). In view of the limited effects that the Stipulation had on Biovail, and the manifestly procompetitive aspects of the Stipulation, Biovail's allegations do not approach that threshold.

## II. BIOVAIL LACKED ANTITRUST STANDING TO CHALLENGE THE STIPULATION.

In *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519 (1983), this Court explained that the antitrust laws do not "encompass every harm that can be attributed directly or indirectly to the consequences of an antitrust violation." *Id.* at 529. Rather, "Congress * * * assumed that antitrust damages litigation would be subject to constraints comparable to well-accepted common law rules applied in comparable litigation" (*id.* at 533; footnote omitted)—rules that "circumscribed the availability of damages recoveries" on grounds such as "foreseeability and proximate cause, directness of injury, [and] certainty of damages". *Id.* at 532 (footnotes omitted).

Even assuming that the allegations in Biovail's counterclaim support the assertion that Biovail suffered antitrust injury, the court of appeals erred by not upholding the dismissal of the counterclaim, with prejudice, on these grounds. Biovail's claim would require a court or jury to engage in an intensely speculative inquiry. Biovail first would require the finder of fact to determine whether Andrx would have entered the market if there had been no interim settlement—a finding that would require speculation about Andrx's willingness to take a great risk; HMRI's willingness to go through with its threat to move for a preliminary injunction; and the district court's likely ruling on that hypothetical motion.

Then, as the district court emphasized, even assuming that the Stipulation delayed Andrx's entry, the finder of fact would have to determine when Andrx would have begun to sell its generic version of Cardizem. See Pet. App. 48a. There is obviously no certainty that Andrx would have gone to market as soon as the thirty-month period expired. Andrx certainly would have considered market conditions in deciding when to take advantage of its exclusivity period (assuming that period was available to it); it might also have considered the progress it was making on the reformulated version of Cardizem.

Finally, and even more speculatively, Biovail would have the finder of fact determine how Biovail would have fared if Andrx had entered the market sooner that it really did. In that counterfactual situation, Andrx would have had a longer head start over Biovail, which did not obtain tentative FDA approval until October 1999. Pet. App. 8a. Biovail would have the finder of fact try to determine what damages Biovail suffered by not being able to compete in such a market. This Court has consistently ordered dismissal when an antitrust plaintiff's "damages claim is * * * [so] highly speculative." *Associated General Contractors*, 459 U.S. at 542; see, e.g., *Blue Shield v. McCready*, 457 U.S. 465, 475 n.11 (1982).

Just as important—and a further reason that Biovail lacks antitrust standing—there is no need to require such speculation. As this Court has repeatedly said, the antitrust laws exist for "the protection of competition, not competitors." *Atlantic Richfield*, 495 U.S. at 338; *Brunswick*, 429 U.S. at 488. Even assuming, wrongly, that the Stipulation was anticompetitive, consumers—as the district court found—would be the parties "most directly affected". Pet. App. 48a. Indeed, since a necessary premise of Biovail's claim is that Andrx kept itself out of the market—where it would have been competing with Biovail and reducing Biovail's profits—Biovail is a peculiarly inappropriate plaintiff in this case.

Class actions purportedly on behalf of consumers challenging the Stipulation are already pending in other courts. See, e.g., *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326 (E.D. Mich. 2001). In *Associated General Contractors*, this Court stated that "[t]he existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement diminishes the justification for allowing a more remote party" to bring suit. 459 U.S. at 542. Here, the "identifiable class of persons" has already brought suit. In these circumstances the court of appeals' rejection of the district court's sensible decision about antitrust standing is manifestly erroneous.

## III. BECAUSE THE STIPULATION WAS A BONA FIDE SETTLEMENT OF PATENT INFRINGEMENT LITIGATION, THE *NOERR-PENNINGTON* DOCTRINE AND THE DOCTRINE OF *STANDARD OIL CO. (INDIANA) v. UNITED STATES* ESTABLISH THAT THERE IS NO ANTITRUST LIABILITY.

A. The court of appeals all but ignored the most significant feature of the Stipulation. The Stipulation was not simply an agreement; it was an interim settlement of litigation, litigation that Biovail did not allege, and the court of appeals did not

suggest, was remotely "sham" litigation brought without any chance of success. See *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993). Andrx was faced with the possibility of losing the patent infringement suit and being unable to market its product at all, and the near-certainty of protracted and expensive litigation before it could market its product without incurring enormous risk. HMRI was faced with the possibility, however remote, that Andrx would proceed to market before the conclusion of the litigation, potentially inflicting irreparable damage on HMRI. In these circumstances the parties entered an interim settlement that included the important and indisputably procompetitive agreement by HMRI to license Andrx's product even if Andrx ultimately lost the patent infringement litigation.

At least since Justice Brandeis's opinion for the Court in *Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931), it has been firmly established that "agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide [intellectual property] dispute." 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046 at 265 (1999); see *Standard Oil Co.*, 283 U.S. at 171 ("Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.").

The reason for this rule is clear. Intellectual property litigation necessarily threatens an exclusionary outcome; that is the nature of an intellectual property claim. It therefore makes no sense to condemn an agreement settling such litigation on the ground that it is exclusionary. Yet that is precisely what the court of appeals did here. Had HMRI obtained a preliminary injunction—a distinct possibility, as neither Biovail nor the court of appeals denied—Andrx would have been kept off the market until the conclusion of the patent litigation. Even if HMRI had not sought a preliminary

injunction, the threat of a crushing damages award could have had the same effect on Andrx. Andrx bargained for, and obtained, an outcome that was far more procompetitive than that: the interim settlement permitted Andrx to obtain a license from HMRI even before the end of the litigation, thus making it possible for Andrx to enter the market sooner.

There may, of course, be some settlement agreements that run afoul of the antitrust laws because they are not bona fide settlements of intellectual property disputes but merely sham settlements. See, e.g., *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963). But it was incumbent on Biovail to allege that the Stipulation was such a non-bona fide agreement—and for the court of appeals to give some reason for believing, for example, that the Stipulation was likely to produce a more anticompetitive outcome than the patent infringement litigation threatened to produce without an interim settlement. No such reason was forthcoming.

B. The *Noerr-Pennington* doctrine also dictates that Biovail is not entitled to assert a Sherman Act claim based on the Stipulation. Under *Noerr-Pennington*, "[t]he federal antitrust laws also do not regulate the conduct of private individuals in seeking anticompetitive action from the government." *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 379-80 (1991). The *Noerr-Pennington* doctrine extends to efforts to bring about allegedly anticompetitive results through litigation. See *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

As other courts of appeals have consistently held, activities that are incident to litigation—including threatening litigation or demanding a favorable settlement—are also protected by *Noerr-Pennington*. See, e.g., *McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d 1552, 1560 (11th Cir. 1992); *Coastal States Marketing, Inc. v. Hunt*, 694 F.2d 1358, 1367 (5th Cir. 1983). The court of appeals, while purporting to acknowledge this point, insisted that the Stipulation was simply a "private

agreement." Pet. App. 26a n.17; see *id.* at 33a-34a . It is true that the settlement was entered without judicial participation, but the court of appeals cited no decision to support its apparent view that a settlement loses *Noerr-Pennington* immunity if it is entered directly between litigants.

Indeed, the Ninth Circuit has stated exactly the opposite: "A decision to accept or reject an offer of settlement is conduct incidental to the prosecution of the suit and not a separate and distinct activity which might form the basis for antitrust liability." *Columbia Pictures Indus., Inc. v. Prof'l. Real Estate Investors, Inc.*, 944 F.2d 1525, 1528 (9th Cir. 1991), *aff'd*, 508 U.S. 49 (1993). The Court appears to have accepted the Ninth Circuit's characterization. See 508 U.S. at 54 n.2. And the Court has explicitly extended *Noerr-Pennington* immunity to "private action" undertaken "independent of * * * government action": "[W]here, independent of any government action, the anticompetitive restraint results directly from private action, the restraint cannot form the basis for antitrust liability if it is 'incidental' to a valid effort to influence government action." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988).

No one has questioned that HMRI's suit was "a valid effort to influence government action," and the settlement agreement was "incidental" to that litigation. "The 'sham' exception to *Noerr* encompasses situations in which persons use governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *City of Columbia*, 499 U.S. at 380 (emphasis in original). Biovail complains only about the outcome of the litigation between HMRI and Andrx—the interim settlement—and not about the fact that HMRI resorted to that process. *Noerr-Pennington*, therefore, required the dismissal of Biovail's attack on the settlement.

The court of appeals did not assert, nor did Biovail allege in its pleading, that the patent infringement litigation was a sham, that the infringement claims were not legitimate, or

that the settlement was not bona fide. The court of appeals nevertheless ruled that that interim settlement may expose Andrx to liability under the antitrust laws. Because the erroneous ruling of the court of appeals will defeat the purposes of an important federal regulatory scheme, and because it is inconsistent with both this Court's decisions and the approach taken in several other circuits, further review is warranted.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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